

**Subcutaneous Infusion Device and Method**

**Technical Field**

5       The present invention relates to an infusion device for delivery of a substance to a patient.

**Background**

10       Infusion devices are used to deliver substances such as medications into the subcutaneous layer of skin of a patient. Typically, an infusion device includes a cannula that is introduced into the skin, as well as a tube extending from the infusion device to, for example, an infusion pump to deliver the substance.

15       In current designs, it is typically necessary to introduce a cannula of the infusion device into the skin while maintaining the device at a given orientation so that the tubing extends in a direction towards the infusion pump. Further, once the infusion device is placed on the skin, there is typically no way to reorient the device and associated tubing, or to remove the tubing from the body without removing the cannula from the skin of the patient. In addition, the profile of infusion devices can be undesirably high, making placement and concealment of the infusion device difficult and uncomfortable to wear. Also, introduction of the infusion device into the skin can be complicated and require two hands to accomplish.

20       It is therefore desirable to provide new designs for infusion devices used to deliver a substance into the skin of a patient.

**Summary**

      Embodiments made in accordance with the present invention are related to infusion devices for delivery of a substance to a patient.

25       In one embodiment, an infusion device can include a site and a set. The site can include a cannula that is introduced into a subcutaneous layer of skin of the patient. The set can be coupled to the site by, for example, placing the set over the site and moving the set from an unlocked to a locked position. A substance can then be

delivered through the set to the site and from the site into the patient through the cannula.

The set can preferably be oriented at multiple rotational orientations with respect to the site, and can preferably be coupled and uncoupled with the site multiple  
5 times.

The above summary of the present invention is not intended to describe each disclosed embodiment or every implementation of the present invention. Figures in the detailed description that follow more particularly exemplify embodiments of the invention. While certain embodiments will be illustrated and described, the invention is  
10 not limited to use in such embodiments.

### **Description of the Drawings**

Figure 1 is a top perspective view of an example embodiment of a site made in accordance with the present invention.

Figure 2 is a bottom perspective view of the site of Figure 1.

15 Figure 3 is a side view of the site of Figure 1.

Figure 4 is a top view of the site of Figure 1.

Figure 5 is a bottom view of the site of Figure 1.

Figure 6 is a cross-sectional view taken along line 6-6 of the site of  
Figure 3.

20 Figure 6A is a cross-sectional view taken along line 6-6 of the site of Figure 3 including a needle used to insert the site.

Figure 7 is an exploded view of the site of Figure 1.

Figure 8 is a top perspective view of a base of the site of Figure 1.

Figure 9 is a bottom perspective view of the base of Figure 8.

25 Figure 10 is a side view of the base of Figure 8.

Figure 11 is a top view of the base of Figure 8.

Figure 12 is a side view of a cannula of the site of Figure 1.

Figure 13 is an end view of the cannula of Figure 13.

Figure 14 is cross-sectional view taken along line 14-14 of the cannula of Figure 12.

Figure 15 is a side view of a diaphragm of the site of Figure 1.

Figure 16 is an end view of the diaphragm of Figure 15.

5        Figure 17 is a cross-sectional view taken along line 17-17 of the diaphragm of Figure 16.

Figure 18 is a top view of an adhesive portion of the site of Figure 1.

Figure 19 is a cross-sectional view taken along line 19-19 of the adhesive portion of Figure 18.

10       Figure 20 is an exploded view of the adhesive portion of Figure 18.

Figure 21 is a top perspective view of an example embodiment of a set in an unlocked position made in accordance with the present invention.

Figure 22 is a top perspective view of a first member of the set of Figure 21.

15       Figure 23 is a top view of the first member of Figure 22.

Figure 24 is a side view of the first member of Figure 22.

Figure 25 is an end view of the first member of Figure 22.

Figure 26 is another end view of the first member of Figure 22.

Figure 27 is a top perspective view of a second member of the set of

20       Figure 21.

Figure 28 is a top view of the second member of Figure 27.

Figure 29 is a side view of the second member of Figure 27.

Figure 30 is an end view of the second member of Figure 27.

Figure 31 is another end view of the second member of Figure 27.

25       Figure 32 is a top view of the set of Figure 21 in an unlocked position.

Figure 33 is a side view of the set of Figure 32.

Figure 34 is an end view of the set of Figure 32.

Figure 35 is a cross-sectional view taken along line 35-35 of the set of Figure 32 with portions of the set removed for clarity.

Figure 36 is a top perspective view of the set of Figure 21 in a locked position.

Figure 37 is a top view of the set of Figure 36.

Figure 38 is a side view of the set of Figure 36.

5 Figure 39 is an end view of the set of Figure 36.

Figure 40 is a bottom perspective view of the set of Figure 36.

Figure 41 is a bottom view of the set of Figure 36.

Figure 42 is a cross-sectional view taken along line 42-42 of the set of Figure 38 with portions of the set removed for clarity.

10 Figure 43 is a perspective view of the site of Figure 1 and the set of Figure 21 coupled to one another.

Figure 44 is a top view of the site and set of Figure 43.

Figure 45 is a bottom view of the site and set of Figure 43.

Figure 46 is a side view of the site and set of Figure 43.

15 Figure 47 is an end view of the site and set of Figure 43.

Figure 48 is another end view of the site and set of Figure 43.

Figure 49 is an exploded perspective view of the site and set of Figure 43.

20 Figure 50 is a cross-sectional view taken along line 50-50 of the site and set of Figure 44.

Figure 51 is an exploded perspective view of another example embodiment of an infusion device including a site and set made in accordance with the present invention.

25 Figure 52 is a perspective view of the infusion device of Figure 51 in a locked position.

Figure 53 is a cross-sectional view of the site of Figure 51.

### **Detailed Description**

Embodiments of the present invention relate to infusion devices for delivering a substance into the subcutaneous layer of skin of a patient.

Generally, the example infusion devices disclosed herein include a site with a cannula that is introduced into the subcutaneous layer of the skin of a patient to deliver a substance, as well as a set that can be coupled to the site to deliver the substance to the site.

5 Referring now to Figures 1-7, an example embodiment of a site 100 of an infusion device is depicted in accordance with the present invention. Generally, the site 100 can be used in conjunction with a set (described below) to deliver a substance into a patient.

The site 100 includes a base 110, a cannula 130, a diaphragm 150, and  
10 an adhesive portion 170. The cannula 130 of the site 100 can be introduced into the subcutaneous layer of skin of the patient using a needle (e.g., needle 139), as shown in Figure 6A. The adhesive portion 170 allows the base 110 of the site 100 to be coupled to the skin of the patient. The diaphragm 150 is in fluid communication with the cannula to deliver a substance from the diaphragm 150, through the cannula 130, and  
15 into the skin of the patient, as described further below.

Referring now to Figures 8-11, the base 110 is shown. The base includes a stand 114 with a top side 111 and a bottom side 112, and forms a central aperture 113 located at a central axis C of the base 110. The stand 114 further forms eight positional slots 115 on the top side 111 positioned radially with respect to the central axis C of the  
20 site 110 at regular intervals.

The base 110 also includes a member 120 coupled to the stand 114, the member 120 being positioned about the central aperture 113 of the stand 114 and including eight surfaces 124. In one preferred embodiment, the member 120 is non-cylindrical in shape. For example, in the embodiment shown the member 120 is  
25 octagonal in shape, although other shapes can also be used, as noted below. The non-cylindrical shape of member 120 defines different mounting orientations for a set that can be coupled to the site 100.

An interior wall of the member 120 forms a cylindrical cavity 121, and an exterior periphery of the member 120 forms a groove 122 extending about the

exterior periphery. In addition, the member 120 forms eight apertures 123 extending from the interior cavity 121 to the groove 122 in the exterior of the member 120.

Referring now to Figures 12-14, the cannula 130 is illustrated. The cannula 130 includes first and second ends 132 and 134. The first end 132 of the  
5 cannula 130 includes a flange portion 136 having a tapered bottom side 140, as well as a tapered portion 138 described further below. The cannula 130 also includes a central bore 142 extending from the first end 132 to the second end 134 to allow a substance to be introduced at the first end 132 and delivered out of the second end 134.

The cannula 130 is positioned within the cavity 121 of the base 110 so  
10 that the bottom taper 140 of the cannula 130 engages tapered bottom surfaces 125 of the cavity 121 of the member 120, and the second end 134 of the cannula 130 extends through the central aperture 113 of the stand 114 at an approximate right angle to the bottom side 112 of the stand 114. See Figure 6. Preferably, the bottom taper 140 of the cannula 130 is positioned adjacent to the stand 114 of the base 110.

15 Preferably the cannula 130 is made of fluorinated ethylene propylene (FEP). Other materials can also be used, such as polytetrafluoroethylene (PTFE), or other suitable plastics.

Referring now to Figures 15-17, the diaphragm 150 is shown. Generally, the diaphragm 150 functions as a septum or seal that allows a needle to access an  
20 internal portion of the septum to deliver a substance provided, for example, from an infusion device or other similar device to the cannula 130.

Preferably, the diaphragm 150 is generally cylindrical in shape and includes an open bottom end 152 and a closed top end 154. The diaphragm 150 also includes a tapered portion 156 adjacent the bottom end 152, and a central reservoir 158.

25 As shown, for example, in Figures 6 and 17, the diaphragm 150 is positioned in the cavity 121 of the member 120 and preferably includes an outer periphery 160 that is sized to frictionally engage the interior cavity wall of the member 120 to retain the diaphragm 150 in the cavity 121. In addition, the tapered portion 156 of the diaphragm 150 is configured to engage the tapered bottom surfaces 125 of the

base 110. The bottom end 152 engages the first end 132 of the cannula 130 to provide fluid communication between the reservoir 158 and the bore 142 of the cannula 130.

More specifically, surfaces 157 adjacent to the bottom end 152 of diaphragm 150 preferably are compressed against the first end 132 of the cannula 130 to provide a seal with respect to the cannula 130 so a substance can be delivered from the diaphragm 150, through the cannula 130, and into the patient. In alternative embodiments, additional structure such as, for example, an O-ring can also be provided between the diaphragm 150 and cannula 130 to provide additional sealing.

In a preferred embodiment, the diaphragm 150 is made of a silicone elastomer. Other materials can also be used, such as ethylene propylene or other suitable elastomeric materials.

As previously noted, preferably the diaphragm 150 is retained in the cavity 121 of the member 120 of the base 110 through the frictional engagement of the outer periphery 160 of the diaphragm 150 with the walls of the cavity 121. In alternative embodiments, a retaining member can be fitted over the open top of the member 120 to further retain the diaphragm 150 in position in the cavity 121. In other embodiments, the diaphragm 150 can be retained in the cavity 121 through compression by other features of the member 120, or the diaphragm 150 can have features that mate with features of the member 120. For example, in one alternative embodiment, the diaphragm 150 can be formed with barbs on the outer periphery 160 positioned and sized to be received within apertures 123 formed in the member 120 to retain the diaphragm 150 in the cavity 120. Other configurations are also possible.

Referring now to Figures 18-20, the adhesive portion 170 is shown. The adhesive portion includes liners 172 and 176 sandwiching a layer 174. Preferably, the layer 174 includes an aperture 178 through which the cannula 130 of the site 100 extends, as described below.

The liner 172 can be removed and the layer 174 coupled to the bottom side 112 of the stand 114 of the base 110 using an adhesive. Examples of such adhesives include, without limitation, acrylic adhesive, synthetic rubber-based adhesive, acrylate adhesive, and silicone-based adhesive. In addition, the liner 176 can be

removed and an adhesive be provided on a bottom side of the layer 174 to couple the adhesive portion 170 and associated site 100 to another adhesive portion or the skin of the patient, for example.

5 In a preferred embodiment, layer 174 of the adhesive portion 170 includes films with adhesives thereon, such as and without limitation, 3M™ 1577 tape. Other materials can also be used.

In an alternative embodiment, layer 174 can be provided with a tab (not shown, but preferably similar to tabs shown on liners 172 and 176) or other similar structure that can assist the patient in removing the layer 174 and associated site 100  
10 from the skin when desired. For example, the tab can extend from an outer periphery of the layer 174 and allow the patient to grasp the tab and thereby peel the layer 174 from the skin to remove the site 100.

In other alternative embodiments, the adhesive portion 170 can be removed completely, and adhesion between the site 100 and skin of the patient can be  
15 provided using film and/or adhesive carried on other structures, such as a device used to insert the site 100 into the body, as described further below.

In other alternative embodiments, the layer 174 can include a foam backing or similar additional material can be added adjacent to the layer 174 to provide supplemental cushioning as the site 100 is inserted into the skin of the patient. Further,  
20 in other embodiments the layer 174 can be replaced or supplemented by one or more other layer of other material such as, for example, a Tegaderm™ film manufactured by 3M™ or an IV3000™ film manufactured by Smith & Nephew.

Referring now to Figure 21, an example embodiment of a set 200 of an infusion device is depicted in accordance with the present invention. As noted  
25 generally above and described further below, the set 200 can be used in conjunction with a site (e.g., site 100) to deliver a substance into a patient.

The set 200 generally includes a first member 210 and a second member 250. The first member 210 is slideable relative to the second member 250 into an unlocked position (see, e.g., Figures 21 and 32-35) and a locked position (see, e.g.,  
30 Figures 36-42), described further below.

Referring now to Figures 22-26, the first member 210 is shown. The first member 210 includes a main body 212, and a port 213 extending through the body 212 and in fluid communication with a hollow needle 214. The port 213 is preferably coupled to a tube (e.g., tube 305 shown in Figure 21) that can be attached, for example,  
5 to an infusion pump for the delivery of a substance to the set 200.

The first member 210 also includes outer arms 220 and 222 with barbs 223 formed on the ends and projections 230 extending below the arms 220. In addition, the first member 210 includes inner arms 226 and 228 with barbs 229. As described further below, the outer arms 220 and 222 can be displaced towards one another when  
10 force is applied to surfaces 221.

Referring now to Figures 27-31, the second member 250 is shown. The second member 250 includes a main body 260, and a central octagonal aperture 270. The second member 250 also includes opening 262 extending to the central aperture 270, as well as openings 264 positioned on opposite sides of the main body 260. The  
15 second member 250 also includes projections 266 formed on a bottom surface 274 of a base 261, as well as slots 268 preferably extending through the base 261 of the main body 260.

Referring now to Figures 21 and 32-35, the first and second members 210 and 250 of the set 200 are shown in the unlocked position. The first member 210 is  
20 slidably received by the second member 250 such that inner arms 226 and 228 are accepted into opening 262 of the second member 250. Projections 230 on outer arms 220 and 222 of the first member 210 are received in slots 268 of the second member 250.

As illustrated by Figure 35, in the unlocked position barbs 229 of inner  
25 arms 226 and 228 of the first member 210 extend through openings 264 and engage shoulders 271 of the second member 250 such that the first and second members 210 and 250 cannot be further separated.

Referring now to Figures 36-42, the first and second members 210 and 250 of the set 200 are shown in the locked position. To move the set 200 from the  
30 unlocked to the locked position, the first and second members 210 and 250 are slid

towards one another, and outer arms 220 and 222 of the first member 210 are accepted into the openings 264 of the second member 250. Likewise, projections 230 on outer arms 220 and 222 slide along slots 268 of the second member 250. Further, surfaces 234 of the inner arms 226 and 228 partially extend into aperture 270, as described further below.

As illustrated by Figure 42, in the locked position outer arms 220 and 222 extend through openings 264 and engage lips 272 of the second member 250. In addition, inner arms 226 and 228 of the first member 210 extend further into the second member 250. In this locked position, the engagement of the barbs 223 with the lips 272 resist allowing the first member 210 from being slid relative to the second member 250.

In order to slide the first member 210 away from the second member 250 from the locked position back to the unlocked position, the outer arms 220 and 222 are deflected inwardly toward one another by applying pressure on surfaces 221 until the barbs 223 clear the lips 272, thereby allowing the first member 210 to be slid with respect to the second member 250 back into the unlocked position as shown in Figures 21 and 32-35.

Preferably, slots 268 formed in the second member 250 include a cammed surface 269 so that projections 230 extending below the arms 220 of the first member 210 are biased towards a first end 267 of the slots 268 to thereby bias the first member 210 into the unlocked position. See Figures 40 and 41. In alternative embodiments, other features can be provided to bias the first member 210 into the unlocked position. For example, detents can be provided to engage barbs 229 as inner arms 226 and 228 of the first member 210 are moved towards the locked position to bias the first member 210 into the unlocked position. It can be preferable to bias the set 200 into the unlocked position so that the set 200 can be easily positioned onto and removed from the site 100, as described further below.

Referring now to Figures 43-50, as previously noted the site 100 and set 200 can be used together to form an infusion device 300 for delivery of a substance to a patient.

One method of use of the infusion device 300 is as follows. Initially, the site 100 is positioned on the skin of a patient with the cannula 130 being introduced into the subcutaneous layer of the skin. This can be accomplished, for example, using a needle (e.g., needle 130 shown in Figure 6A) that is extended through the exposed  
5 closed end 154 of the diaphragm 150 and through the bore 142 of the cannula 130 and beyond the second end 134. The tapered portion 138 of the flange portion 136 of the cannula 130 can assist in directing the needle through into the bore 142 of the cannula 130. In this position, the needle can be used to introduce the cannula 130 of the site 100 into the skin of the patient. Further, once the cannula 130 is in position, the needle can  
10 be removed, leaving the cannula 130 in place in the subcutaneous layer of the skin. As the needle is removed, the closed end 154 of the diaphragm 150 reseals itself to retain the fluid-tight reservoir 158.

In a preferred embodiment, the site 100 of the infusion device 300 is placed in position on the skin of a patient using a device made in accordance with that  
15 disclosed in U.S. Patent Application Serial No. 10/\_\_\_\_,\_\_\_\_, Attorney Docket No. 14485.154US01, entitled "Device and Method for Insertion of a Cannula of an Infusion Device," filed on even date herewith, the entirety of which is hereby incorporated by reference. Other methods and devices for inserting the infusion device into the skin of the patient can also be used. For example, in an alternative embodiment the site 100  
20 can be inserted manually using a needle. See needle 139 shown in Figure 6A.

Once the site 100 has been positioned on the skin of a patient (with the cannula 130 having been introduced into the subcutaneous layer), the set 200 can be coupled to the site 100 as follows. With the set 200 in the unlocked position, the set 200 can be placed over the member 120 so that the central octagonal aperture 270 of the  
25 set 200 accepts the member 120 into the aperture 270. The set 200 is lowered onto the site 100 until the bottom surface 274 of the set 200 contacts the stand 114 of the site 100 and projections 266 of the second member 250 are accepted into the positional slots 115 of the stand 114 of the base 110.

In this position on the site 100, the first member 210 of the set 200 can  
30 be slid from the unlocked to the locked position. As the first member 210 is slid to the

locked position, surfaces 234 of the inner arms 226 and 228 (see Figures 23, 36, and 37) are accepted by the groove 112 of the member 120 of the base 100, which locks the set 200 to the site 100 so that the set 200 resists any upward force tending to remove the set 200 from the site 100 when the set 200 is in the locked position. In addition, the shape of the member 120 of the site 100 and the central aperture 270 of the set 200, as well as projections 266 received in slots 115, orient the set 200 with respect to the site 100 and function to resist rotation of the set 200 with respect to the site 100 when the set 200 is in the locked position.

In addition, as the first member 210 of the set 200 is moved from the unlocked to the locked position, the needle 214 is advanced through one of the eight apertures 123 formed in the member 120 and into the diaphragm 150 in the cavity 121. In the fully locked position as shown in Figure 50, an end 215 of the needle 214 is positioned within the reservoir 158 of the diaphragm 150. In this position, the port 213 is fluidly coupled to the cavity 121 of the diaphragm 150 through the hollow needle 214, and the cavity 121 is in turn fluidly coupled to the skin of the patient through the bore 142 in the cannula 130. In this manner, a substance can be delivered to the port 213 of the set 200 (by, for example, a tube not shown in the figures), through the needle 214, into the reservoir 158, and into the subcutaneous layer of the skin of the patient by the cannula 130.

If the set 200 is not oriented as desired with respect to the site 100, or if the patient desires to remove the set 200 from the site 100, the set 200 can be moved from the locked to the unlocked position by forcing the outer arms 220 and 222 together and sliding the first member 210 away from the second member 250 to the unlocked position. This action removes the surfaces 234 from the groove 122, as well as the needle 214 from the reservoir 158. The diaphragm 150 reseals upon removal of the needle 214. The set 200 can then be removed from the site 100, leaving the site 100 in place on the skin of the patient. The set 200 can be replaced at another orientation or at a later time.

In the illustrated embodiment of the infusion device 300, the set 200 can be oriented in eight different positions with respect to the site 100. In alternative

embodiments, the site 100 and set 200 can be configured to include fewer or more positions as desired. For example, in an alternative embodiment the member 120 of the site 100 and the aperture 270 of the set 200 can be formed in the shape of a square if four orientational positions are desired.

5                   Referring now to Figures 51-53, another example infusion device 400 is shown in accordance with the present invention. The device 400 is similar to the example device 300 described above, except for the details noted below.

                  The infusion device 400 includes a site 405 with a central portion 407. The central portion 407 includes a pierceable outer shell 430 made of a material such as a plastic, and a softer inner diaphragm 432 surrounding the outer shell 430. An inner  
10                   reservoir 434 of the central portion 407 is fluidly coupled to a cannula 440. See Figure 53.

                  The infusion device 400 also includes a set with a first member 410 and a second member 420. The first member 410 includes a needle 411, and first and  
15                   second arms 412 and 414 with barbs 415 on ends. The second member 420 includes shoulders 422 and 424. The first and second members 410 and 420 each form openings 461 and 462, respectively, that are sized to each receive a portion of the central portion 407 of the site 405.

                  The infusion device 400 can be used as follows. First, the site 405 is  
20                   positioned on the skin of a patient so that the cannula 440 is introduced into the subcutaneous layer. Next, the first member 410 and second member 420 of the site are placed onto the site 405 so that openings 461 and 462 are positioned about the central portion 407, and the first and second members 410 and 420 are slid towards one another from the unlocked to the locked position. As the set is moved to the locked position,  
25                   the needle 411 is introduced into the central portion 407 of the site 405, moving through the outer shell 430 and into the reservoir 434 to become fluidly coupled to the cannula 440. In addition, the arms 412 and 414 are accepted into the second member 420 until barbs 415 engage the shoulders 422 and 424 in the locked position, as shown in Figure 52.

To move the set from the locked position back into the unlocked position, the barbs 415 are pressed inwardly toward one another until they clear the shoulders 422 and 424, and then the first member 410 is slid away from the second member 420, thereby removing the needle 411 from the central portion 407 of the site 405.

As preferably there is no specific structure provided with infusion device 400 for rotationally orienting the set with the site 405, the set can be oriented at an infinite number of rotational positions with respect to the site 405 as desired. Further, since the central portion 407 of the site and the openings 461 and 462 of the set are preferably circular in shape, the first and second members 410 and 420 of the site can be rotated relative to the site 405 without requiring that the set be completely removed from the site 405.

Infusion devices made in accordance with the principles described herein can be advantageous for various reasons. For example, the set can be coupled in various selectable rotational orientations with respect to the site. In some embodiments, a plurality of orientations can be provided. This allows a patient to rotationally orient the set (and associated tube coupled to the set) as desired so that the tube can extend, for example, towards an infusion pump regardless of where the site is placed on the body of the patient.

In addition, the set and associated tube can be removed from the site multiple times while leaving the site on the skin. This can be desirable if the patient wants to reorient the set with respect to the site, or if the patient wants to remove the set from the site for a period of time, such as if the patient wishes to shower and then replace the set onto the site.

The engagement of the set with the site and sliding action of the set from the unlocked to locked position can also be advantageous in that a patient can preferably accomplish orientation and coupling of the set to the site using a single hand. This can be preferable, for example, if the site has been placed on a portion of the body of the patient that is not easily reached using two hands, or cannot easily be seen by the patient (e.g., if the site is placed on the back of the patient).

Further, the configuration of the set functions to protect the patient from inadvertent contact with the hollow needle (e.g., needles 214 and 411) used to pierce the diaphragm and deliver the substance to the site. For example, the outer arms 220 and 222 and the inner arms 226 and 228 of the first member 210 of the set 200 generally surround the needle 214 and function to reduce the chance that the patient will inadvertently contact the needle.

Also, the configuration of the diaphragm in the site can be preferable in that a single diaphragm can function to both allow introduction of the cannula of the site into the body using one needle, as well as coupling of the set with the site using a second needle. In addition, the diaphragm can preferably be held within the site through frictional engagement between the diaphragm and the site without requiring additional structure to retain the diaphragm in the site.

Although examples of infusion devices have been described herein, various modifications can be made to the devices. For example, as noted above the member 120 of the site 100 and the aperture 270 of the set 200 can be formed in a variety of shapes to allow the set 200 to be oriented in multiple positions with respect to the site 100. In addition, a retaining member can be fitted over the open top of the member 120 to further retain the diaphragm 150 in position in the cavity 121

In another alternative embodiment, the second member 250 of the site 200 can be constructed to include a cover portion extending from the main body 260 so that when the set 200 is moved to the locked position the cover extends over the closed end 154 of the diaphragm 150 to reduce exposure of the set and site to outside contaminants.

The above specification, examples and data provide a complete description of the manufacture and of the invention. Since many embodiments of the invention can be made without departing from the spirit and scope of the invention, the invention resides in the claims hereinafter appended.